Clinical Presentation – 10/22/2021

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Androgenic Agents

- There is no recent information of significance in this class since the last time the class was reviewed.

Antibiotics, GI

- Alinia is now available as a generic.
- Aemcolo (rifamycin delayed-release tablets) has been approved for the treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* in adults. It is not recommended for patients with diarrhea complicated by fever and/or bloody stool or due to other pathogens. It is approved as 194 mg delayed-release tablet. It is dosed as two tablets (388 mg) orally twice daily for three days. Contraindications include history of hypersensitivity to rifamycin, rifamycin class antimicrobials, or any components of Aemcolo. Warnings include risk of persistent or worsening diarrhea complicated by fever and/or bloody stool and *Clostridium difficile*-associated diarrhea. Common adverse reactions observed are headache and constipation. No comparative clinical data available.
- Solosec (secnidazole) is now approved to treat trichomoniasis caused by *Trichomoniasis vaginalis* in adults. Solosec was already approved for the treatment of bacterial vaginosis in adult women. The recommended dose for treatment of trichomoniasis is a single 2 g packet once orally without regard to meals. Sexual partners should be treated with the same dose and at the same time.

Antibiotics, Topical

- There is no recent information of significance in this class since the last time the class was reviewed.

Antibiotics, Vaginal

- Vandazole (metronidazole) is now approved for the treatment of bacterial vaginosis is post-menarchal females. The previous indication was for the treatment of bacterial vaginosis in non-pregnant women. The indication no longer excludes pregnant women.

Anticonvulsants

- Elepsia XR (levetiracetam) FDA approved for the adjunctive treatment of partial-onset seizures in patients ≥ 12 years old. Approved as 1,000 and 1,500 mg ER tablets; dosed as 1,000 mg once daily, increasing by 1,000 mg every 2 weeks to a maximum recommended dose of 3,000 mg once daily (taken whole). It is not recommended for use in patients with moderate or severe renal impairment; the maximum recommended dose in patients with mild renal impairment is 2,000 mg.
- Vimpat (lacosamide) is now approved for adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients ≥ 4 years of age. It was previously only indicated for the treatment of partial-onset seizures in patients ≥ 4 years of age. In adults, the initial dose for the new indication is 50 mg twice daily. In pediatric patients, the recommended dose is weight-based and given orally twice daily with a maintenance dose for patients weighing ≥ 50 kg targeting 100 to 200 mg twice daily.
- Levetiracetam (Spritam) is now indicated for the treatment of partial-onset seizures (POS) in patients ≥ 4 years old weighing > 20 kg. It was previously indicated for POS as adjunctive therapy in patients with epilepsy ≥ 4 years old weighing > 20 kg. It is also indicated as adjunctive therapy for myoclonic seizures in patients ≥ 12 years old with juvenile myoclonic epilepsy and as adjunctive therapy for primary generalized tonic-clonic seizures in patients ≥ 6 years with idiopathic generalized epilepsy. Dosing is the same for POS when used as adjunctive therapy or monotherapy and is 500 mg twice daily, increased as needed/tolerated by 500 mg twice daily every 2 weeks to a maximum recommended dose of 1,500 mg twice daily for adults/pediatric patients ≥ 4 years weighing > 40 kg. For pediatric patients ≥ 4 years weighing 20 to 40 kg, the dosing is 250 mg twice daily, increased by 250 mg twice daily every 2 weeks to a maximum of 750 mg twice daily.
- The FDA issued a Drug Safety Communication for lamotrigine (Lamictal) regarding a potential increased risk of arrhythmias in patients with heart disease as a result of reports of abnormal ECGs. The FDA will continue to evaluate and inform the public and healthcare professionals of their findings as more required in vitro studies are available. Healthcare providers should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient.
- Banzel (rufinamide)is now available as a generic.

Antiemetics/Antivertigo Agents

- Gimoti, a metoclopramide nasal spray, indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. It is not recommended for use in pediatric patients due to the potential for tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates. Additionally, it is not recommended for use in moderate or severe hepatic impairment (Child-Pugh B or C), moderate or severe renal impairment (creatinine clearance < 60 mL/minute), and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and side

effects. Supplied as a nasal spray containing 15 mg of metoclopramide in each 70 microliter spray. For adults < 65 years of age, recommended dosage is 1 spray (15 mg) in 1 nostril, 30 minutes prior to each meal and at bedtime (max of 4 sprays daily) for 2 to 8 weeks, depending on response. For adults ≥ 65 years of age, it is not recommended as initial therapy; however, geriatric patients receiving an alternative metoclopramide formulation at a stable dosage of 10 mg four times daily can be switched to Gimoti 1 spray (15 mg) in 1 nostril, 30 minutes prior to each meal and at bedtime (max 4 times daily) for 2 to 8 weeks, depending on response.

Antifungals, Oral

- Brexafemme (ibrexafungerp), a triterpenoid antifungal, is indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC). It is supplied as a 150 mg oral tablet and the recommended dose is 300 mg twice a day for one day for a total treatment dosage of 600 mg. It can be taken with or without food, and the pregnancy status in females of reproductive potential should be verified before starting therapy. Contraindications include pregnancy and hypersensitivity reactions. Warnings include risk of fetal toxicity. The most commonly reported adverse reactions were diarrhea, nausea, vomiting, abdominal pain, and dizziness.
- Noxafil (delayed-release posaconazole) is now approved for the prophylaxis for invasive Aspergillus and Candida infections in patients ≥ 13 years old who are at high risk of developing these infections due to being severely immunocompromised to include peds patients ≥ 2 years old who weigh > 40 kg. The recommended dosing of the delayed-release tablet for pediatric patients 2 to < 18 years of age is a loading dose of 300 mg twice daily on the first day, followed by maintenance dose of 300 mg once daily. The duration of therapy is dependent on recovery from neutropenia or immunosuppression.
- Noxafil (delayed-release posaconazole) is now approved for the treatment of invasive Aspergillus in patients ≥ 13 years of age. It was previously approved for the prophylaxis of Aspergillus and Candida infections. For the treatment indication, the recommended dose is 300 mg twice daily on day 1 followed by 300 mg once daily for a total duration of 6 to 12 weeks.

Antifungals, Topical

- Triamazole™ (econazole / triamcinolone acetonide), an antifungal agent co-packaged with topical corticosteroid triamcinolone 0.1% ointment, is indicated for the relief of inflammatory and pruritic manifestations of corticosteroids responsive dermatosis.

Antihistamines - first generation

- There is no recent information of significance in this class since the last time the class was reviewed.

Antiparasitics, Topical

- Natroba (spinosad) is now approved for the topical treatment of scabies infestations in adult and pediatric patients 4 years of age and older. It was previously only approved for the topical treatment of head lice infestations in adults and pediatric patients ≥ 6 months of age. The recommended use for the treatment of scabies infestations is as follows: shake the bottle well, apply topically to the skin and rubbing it in completely covering the body from the neck down to the soles of the feet, allow for the

product to absorb and dry for 10 minutes prior to getting dressed, leave product on the skin for a minimum of 6 hours before showering or bathing. For patients with balding scalp, apply to the scalp, hairline, temples, and forehead. Adjunctive measures for scabies infestations include washing any bedding, clothing, and towels used by affected person in hot water or via dry-cleaning. Corresponding efficacy and safety updates made throughout product labeling, including updates to the warning on benzyl alcohol.

Antipsychotics

- FDA approved an every-6-month injection for the treatment of schizophrenia in adults after they have been adequately treated with Invega Sustenna (once-monthly) or Invega Trinza (every-3-month) regimen. Approved as injectable suspension in 1,092 mg/3.5 mL and 1,560 mg/5 mL single-dose prefilled syringes.

Antivirals, Topical

- There is no recent information of significance in this class since the last time the class was reviewed.

Bone Resorption Suppression

- There is no recent information of significance in this class since the last time the class was reviewed.

Colony Stimulating Factors

- There is no recent information of significance in this class since the last time the class was reviewed.

Epinephrine, Self-Injected

- There is no recent information of significance in this class since the last time the class was reviewed.

GI Motility, Chronic

- There is no recent information of significance in this class since the last time the class was reviewed.

Growth Hormone

- There is no recent information of significance in this class since the last time the class was reviewed.

Hepatitis C

- Epclusa (sofosbuvir/velpatasvir) is now approved for the treatment of HCV genotypes 1,2,3,4,5, and 6 in patients ≥ 3 years of age without cirrhosis or with decompensated cirrhosis when used in combination with ribavirin. It was previously approved for use in patients ≥ 6 years of age. The recommended once daily dosing for patients 3 to ≤ 6 years of age is weight-based. For patients weighing < 17 kg, the recommended dose is 150/37.5mg, for patients weighing 17 kg to < 30 kg the recommended dose is 200/50 mg and for ≥ 30 kg is 400/100 mg. When used in combination with ribavirin, weight-based daily dosing divided into 2 equal doses is 15 mg for < 47 kg, 600 mg for 47-49 kg, 800 mg for 50-65 kg, 1000 mg for 66-80 kg and 1,200 mg for > 80 kg. Two additional strengths of oral pellets were approved containing 200/50 mg and 150/37.5 mg for the lower dose ranges. Oral pellets can be taken directly in the mouth or

with food. In patients < 6 years of age, it is recommended to take the pellets with food to improve tolerability and palatability by sprinkling the packet on one or more spoonsful of non-acidic soft food.

- Mavyret (glecaprevir/pibrentasvir) is now approved for use in patients as young as 3 years of age who have HCV genotype 1-6 without cirrhosis or with compensated cirrhosis or with HCV genotype 1 who had prior treatment with an HCV NS5A inhibitor or NS3/4A protease inhibitor, but not both. It was previously approved for use in patients ≥ 12 years of age. For patients 3 to < 12 years of age, dosing is weight-based. In patients < 20 kg, the recommended daily dose is 150/60 mg, for patients 20 kg to < 30 kg is 200/80 mg, 30 kg to < 45 kg is 250/100 mg, and for patients ≥ 45 kg the dosing is 300/120 mg. Mavyret oral pellets were approved in 50/20 mg per packet to accommodate dosing in the younger population. Oral pellets are intended for use in patients < 12 years of age and < 45 kg.

HIV/AIDS

- The International Antiviral Society–USA Panel has published 2020 recommendations on the use of antiretroviral drugs for treatment and prevention of HIV infection in adults. The updated recommendations address new evidence since the prior publication of recommendations in 2018. For all individuals with HIV who have detectable viremia, antiretroviral therapy (ART) is recommended to be initiated as soon as possible. The majority of patients are eligible for treatment initiation with either a 3-drug or 2-drug regimen, including an integrase strand transfer inhibitor. Additionally, there are treatment options available for special populations of patients (e.g., pregnant women, patients with kidney, liver, or CV disease, those with opportunistic infections, those with healthcare access challenges). Currently, switching therapy due to virological failure is generally rare; however, the recommendations for switching therapies due to convenience or for other reasons are addressed. Preexposure prophylaxis with an oral regimen is recommended for individuals at risk for HIV.
- Selzentry (maraviroc) is now approved to treat HIV-1 infection in pediatric patients weighting a least 2 kg. It was previously approved for use only in patients 2 years of age and older weighing at least 10 kg. The recommended dosing for the expanded pediatric population is based on weight and concomitant medications due to drug interactions. Selzentry is not recommended in combination with select agents due to drug interactions. All doses are administered twice daily ranging from 30 mg to 100 mg twice daily for the new population (2 to <10 kg). An additional 3 mL oral dosing syringe will be provided with the 10 mL oral dosing syringe in a Convenience Combination Kit.
- Gilead has announced that it will be discontinuing Atripla as of July 2021. Supply is expected to be available until December 2021.
- Dovato (dolutegravir/lamivudine) is now approved for use in HIV-1 infected patients with renal impairment and creatinine clearance of ≥ 30 to 49 mL/min. Dovato was not previously approved for use in patients with creatinine clearance < 50 mL/min. Dovato is a fixed dose tablet containing 50 mg of dolutegravir and 300 mg of lamivudine. The recommended dose for adults is 1 tablet orally once daily with or without food.
- Triumeq (abacavir/dolutegravir/lamivudine) is now approved for use in HIV-1 infected patients with renal impairment and creatinine clearance of ≥ 30 to 49 mL/min. Triumeq was not previously approved for use in patients with creatinine clearance < 50 mL/min. Triumeq is a fixed dose tablet containing 600 mg of

abacavir, 50 mg of dolutegravir and 300 mg of lamivudine. The recommended dose for adults and pediatric patients weighing ≥ 40kg is 1 tablet orally once daily with or without food.

- The FDA announced that BMS will discontinue Reyataz 150mg. Supply is expected to be available until December 2021. Generic versions will remain available.

Hypoglycemics, Insulin and related

- Semglee (insulin glargine-yfgn) is now approved as an interchangeable biosimilar to insulin glargine (Lantus). Semglee is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with T1DM and in adults with T2DM; it is not recommended for treating diabetic ketoacidosis. An interchangeable biosimilar product may be substituted for the reference product without the intervention of the prescriber, at the pharmacy, depending on state pharmacy substitution laws. It is supplied as 100 units/mL (U-100) in a 10 mL MDV and 3 mL single-patient-use prefilled pen. Dosage is individualized based on metabolic needs, blood glucose (BG) monitoring, glycemic control, diabetes type, and previous insulin use with administration given SC into the abdominal area, thigh, or deltoid once daily at any time of day, but at the same time every day. Careful monitoring of BG is recommended when switching to Semglee and during the first weeks after switching.
- The USPSTF has issued a final recommendation statement on screening for prediabetes and type 2 diabetes. It is recommended to screen for prediabetes and type 2 diabetes in adults aged 35 to 70 years who are overweight or obese, and health care providers should offer or refer patients with prediabetes for preventive interventions (Grade B).

Hypoglycemics, Meglitinides

- There is no recent information of significance in this class since the last time the class was reviewed.

Hypoglycemics, Metformins

- The USPSTF has issued a final recommendation statement on screening for prediabetes and type 2 diabetes. It is recommended to screen for prediabetes and type 2 diabetes in adults aged 35 to 70 years who are overweight or obese, and health care providers should offer or refer patients with prediabetes for preventive interventions (Grade B).

Hypoglycemics, sodium-glucose cotranporter-2 inhibitors (SGLT2)

- The American Diabetes Association (ADA) updated select sections of their living Standards of Medical Care in Diabetes - 2020. For diabetes technology, an automated insulin delivery system should be considered in adults with T1DM who have the skills to use the device in order to improve time in range and reduce A1C and hypoglycemia (A-rated recommendation). These systems may also be useful to improve glycemia in children (B-rated recommendation). Regarding obesity management, ADA states that lorcaserin should no longer be used, as the FDA requested its market withdrawal. For pharmacologic T2DM therapy, ADA advises to interrupt SGLT2 inhibitor therapy before scheduled surgery to avoid diabetic ketoacidosis, this aligns with label revisions for SGLT2 inhibitors. For

management of CVD in patients with T2DM, ADA advises to consider an SGLT2 inhibitor in patients with HF with reduced ejection fraction to reduce risk of worsening HF and CV death.

- The Kidney Disease: Improving Global Outcomes (KDIGO) organization published its first guidelines on managing diabetes in patients with chronic kidney disease (CKD). Key recommendations include patients with diabetes, hypertension, and albuminuria should start treatment with an ACEI or ARB; in patients with diabetes and CKD, monitor glycemic control using HbA1c to a target range from < 6.5% to < 8% in those not on dialysis depending on hypoglycemia risk; metformin and a SGLT2 inhibitor are recommended in patients with eGFR ≥ 30 mL/min/1.7 m2; if glycemic targets are not met, then a long-acting GLP-1 agonist is recommended.
- The American College of Cardiology (ACC) updated their 2017 Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment addressing 10 pivotal issues in heart failure with reduced ejection fraction (HFrEF) including: (1) initiating, adding, or switching therapies to evidence-based treatments; (2) optimal therapy given multiple drugs; (3) when to refer to a specialist; (4) addressing challenges of care coordination; (5) improving medication adherence; (6) specific patient cohorts; (7) managing cost and access; (8) managing complexity; (9) managing comorbidities; and (10) integrating palliative/hospice care. The update addresses expanded data since the 2017 publication on ARNIs and SGLT2 inhibitors, resulting in updated/inclusion of target dosing and algorithms. Table 2 includes indications for ARNI, ivabradine, and SGLT2 inhibitor use. ARNI's are recommended when HFrEF (EF ≤ 40%), NYHA class II–IV, and when administered in conjunction with a background of guideline-directed medical therapy (GDMT) in place of an ACEI or ARB. Ivabradine is recommended for HFrEF (EF ≤ 35%), NYHA class II or III, with a maximum dose of beta-blocker, and sinus rhythm with resting HR ≥ 70 bpm. SGLT2 inhibitors are recommended for HFrEF (EF ≤ 40%) with or without diabetes, NYHA class II–IV, and when administered in conjunction with background GDMT. Additional population selection (e.g., contraindications) for these medications is also provided as well as target dosing/dose adjustments for sacubitril/valsartan.
- FDA approved new indication for Farxiga (dapagliflozin) to reduce the risk of sustained eGFR decline, end stage kidney disease (ESKD), CV death, and hospitalization for heart failure (hHF) in adults with chronic kidney disease (CKD) at risk of progression. Corresponding new limitations of use were also added stating that dapagliflozin is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR < 45 mL/min/1.73 m2 as it is unlikely to be effective based upon its mechanism of action. It also carries a limitation of use stating it is not recommended for the treatment of CKD in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for the treatment of kidney disease as it is not expected to be effective in these populations. Recommended dosage is based on eGFR and indication for use. For patients with eGFR ≥ 45 mL/min/1.73m2, for improving glycemic control, the recommended starting dose is 5 mg orally once daily and the dose can be increased to 10 mg orally once daily for additional glycemic control; for all other indications in patients with eGFR ≥ 45 mL/min/1.73m2, the recommended starting dose is 10 mg orally once daily. For patients with eGFR 25 to < 45 mL/min/1.73m2, 10 mg orally once daily. For patients with eGFR < 25 mL/min/1.73m2, starting therapy is not recommended; however, patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, CV death, and hHF. It is contraindicated in those on dialysis.

- Jardiance (empagliflozin) is now approved to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction (HFrEF). The clinical trial that supported this indication included patients with and without T2DM. The recommended dose is 10 mg once daily in the morning and may be increased for glycemic control.
- The USPSTF has issued a final recommendation statement on screening for prediabetes and type 2 diabetes. It is recommended to screen for prediabetes and type 2 diabetes in adults aged 35 to 70 years who are overweight or obese, and health care providers should offer or refer patients with prediabetes for preventive interventions (Grade B).

Hypoglycemics, thiazolidinedione (TZD)

- There is no recent information of significance in this class since the last time the class was reviewed.

Macrolides/Ketolides

- The Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR) published guidelines on the prevention, diagnosis, and treatment of Lyme disease. Following a high-risk bite in all age groups, a single dose of oral doxycycline (200 mg adult; 4.4 mg/kg [max 200 mg] for pediatrics) within 72 hours of tick removal is recommended over observation. For erythema migrans, they recommend oral antibiotic therapy (first line: doxycycline, amoxicillin, or cefuroxime axetil; second-line: azithromycin if unable to take first-line medications; duration 5 to 14 days, depending on medication). For Lyme arthritis, oral antibiotics for 28 days are recommended. The full guidelines provide additional recommendations, such as IV therapy for Lyme disease-associated meningitis, cranial neuropathy, radiculoneuropathy or with other peripheral nervous system manifestations, parenchymal involvement, recurrent or refractory patients, or Lyme carditis, as well as non-pharmacologic recommendations.

Opiate Dependence Treatments

- Kloxxado (naloxone nasal) is a higher dose naloxone nasal spray that delivers 8 mg to treat opioid overdose. It was approved through a 505(b)(2) NDA. Naloxone nasal spray was previously only approved in 2mg and 4mg products.

Tetracyclines

- Nuzyra (omadacycline) now includes an oral loading dose option with the tablets: 300 mg orally twice on day 1. Previously, the injection formulation was required for the loading dose in CABP patients. The labeling already included a maintenance oral dose for CABP of 300 mg orally once daily for 7-14 days.

SINGLE PRODUCT REVIEWS

- Benlysta Autoinjector (subcutaneous) / Immunosuppressives: Benlysta (belimumab) is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active, autoantibody positive systemic lupus erythematosus (SLE) who are receiving standard therapy, as well as treatment of adult patients with active lupus nephritis who are receiving standard therapy.

Benlysta is administered intravenously (IV) to adults with SLE or lupus nephritis and pediatric patients with SLE at a dose of 10 mg/kg every 2 weeks for the first 3 doses, then every 4 weeks thereafter. Benlysta can also be administered subcutaneously for the treatment of SLE in adults at a dose of 200 mg weekly. Warnings and Precautions include serious infections, progressive multifocal leukoencephalopathy (PML), hypersensitivity reactions, depression and suicidality, and live vaccines should not be given concurrently with Benlysta. The most common adverse events reported with Benlysta in adults and pediatric patients include (incidence ≥ 5%) nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, extremity pain, depression, migraine, pharyngitis, and injection site reactions.

- Lumakras (oral) /Oncology, oral – lung Lumakras (sotorasib) is an inhibitor of the RAS GTPase family and is approved for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy. It is available as 120 mg tablets and is dosed as 960 mg orally once daily until disease progression or unacceptable toxicity. There are no contraindications. Warnings include hepatotoxicity and interstitial lung disease. The most commonly reported adverse reactions were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough.
- Lupkynis (oral) / Immunosuppressives: Lupkynis (voclosporin) is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). The safety and efficacy of its use in combination with cyclophosphamide has not been established. Use of Lupkynis is contraindicated with concomitant use of strong cytochrome (CYP) 3A4 inhibitors due to the risk for significant increases in exposure that may increase the risk of adverse reactions, such as acute/chronic nephrotoxicity, as well as in patients with a prior hypersensitivity reaction to it. Lupkynis carries a boxed warning for the risk of developing serious infections and malignancies. Recommended dosing is 23.7 mg given twice daily on an empty stomach, as close to a 12-hour schedule as possible, with a minimum of 8 hours between doses. Dosing of Lupkynis is based on a patient's estimated glomerular filtration rate (eGFR), which should be assessed every 2 weeks for the first month, then every 4 weeks thereafter. For patients with no clinical benefit after 24 weeks, therapy should be discontinued. Warnings and precautions include lymphoma and other malignancies, serious infections, nephrotoxicity, neurotoxicity, hypertension, hyperkalemia, QTc prolongation, and pure red cell aplasia. Lupkynis should not be administered concurrently with live vaccines. The most common adverse reactions (incidence ≥ 3%) include: decrease in GFR, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, upper abdominal pain, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.
- Truseltiq (oral) / Oncology, oral – other Truseltiq (infigratinib) is a kinase inhibitor approved for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth receptor factor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test. The presence of an FGFR2 fusion or rearrangement should be confirmed before starting therapy. Infigratinib will be supplied as 25mg & 100 mg oral capsules. The recommended dose is 125 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28 day cycles continued until disease progression or unacceptable toxicity. Capsules should be taken on

an empty stomach at least one hour before or 2 hours following food at about the same time every day and swallowed whole with a glass of water. The capsules should not be crushed, chewed, or dissolved. There are no contraindications. Warnings include ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity. The most commonly reported adverse reactions were nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodyesthesia syndrome, arthralgia, dysgeusia, constipation, abdominal pain, dry mouth, eyelash changes, diarrhea, decreased appetite, blurred vision, and vomiting.

- Zegalogue / Glucagon agents FDA approved Zegalogue, an anti-hypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged ≥ 6 years. Approved as a 0.6 mg/0.6 mL single-dose autoinjector and a 0.6 mg/0.6 mL single-dose prefilled syringe; dosed as 0.6 mg SC once, calling for emergency assistance immediately after administering. If there is no response after 15 minutes, an additional dose may be given while waiting for emergency assistance.

This concludes the Therapeutic and Clinical Drug reviews and Updates.